Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

MAILED

FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON DC 20007

SEP 2 3 2009
OFFICE OF PETITIONS

In re Patent No. 7,541,153

: DECISION ON REQUEST FOR

Fukui et al.

: RECONSIDERATION OF

Issue Date: June 2, 2009

: PATENT TERM ADJUSTMENT

Application No. 10/535,223

: AND NOTICE OF INTENT TO ISSUE

Filed: March 27, 2006

: CERTIFICATE OF CORRECTION

Docket No.024918-0123

:

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705, filed July 29, 2009, which is properly treated under 37 CFR 1.705(d). Patentees request that the determination of patent term adjustment for the above-identified patent be corrected from three hundred twenty-five (325) days to six hundred ninety-seven (697) days.

Preliminarily, patentees request that the Office defer or delay a decision on this request for reconsideration until a final decision has been rendered in Wyeth v. Dudas, 580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008), which is now on appeal at the U.S. Court of Appeals for the Federal Circuit, under Federal Circuit Docket No. 2009-1120. However, the Office notes that there is no specific regulatory provision for requesting that a petition under 37 CFR 1.705(d) be held in abeyance.

The request for reconsideration of the patent term adjustment indicated in the patent is **GRANTED** to the extent indicated herein.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond. No extensions of time will be granted under 37 CFR 1.136.

The patent term adjustment indicated on the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of **371 days**.

On June 2, 2009, the above-identified application matured into U.S. Patent No. 7,541,153. The patent issued with a revised patent term adjustment of 325 days. The present request for reconsideration of patent term adjustment was timely filed on July 29, 2009, within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees aver that the correct number of days of Patent Term Adjustment is 697 days under the court's interpretation of the overlap provision as set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the total non-overlapping PTO delay under 35 U.S.C. 154(b)(1)(A) (326 days) and 35 U.S.C. 154(b)(1)(B) (372 days) is 698 days as these periods do not occur on the same day. Further, given the applicant delay of 1 day, patentees assert entitlement to 697 (698-1) days of patent term adjustment.

At the outset, the Office concurs with patentees that the period of delay under 37 CFR 1.702(b) is 372 days. A review of the record indicates that the Office did not use the 35 U.S.C. 371(b) national stage commencement date of Thursday, May 26, 2005, in calculating the period of adjustment under 37 CFR 1.703(b). As stated in 37 CFR 1.703(b), the period of adjustment under § 1.702(b) is the number of days in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued.

Pursuant to 37 CFR 1.703(b), the period of adjustment under 37 CFR $1.702(b)^{1}$ should be 372 days, counting the number of days beginning

Pursuant to 35 U.S.C. 154(b)(1)(B), 37 CFR 1.702(b) provides, in pertinent part, that:

on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b), May 27, 2008, and ending on the date the patent issued, June 2, 2009.

As to patentees' interpretation of the period of overlap, the Office finds it inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f)² and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap

Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application[.]

² Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154 (b) (2) (A), 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 $U.S.C.\ 154(b)(2)(A)$, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 $U.S.C.\ 154(b)(1)(B)$, the entire period during which the application was pending before the Office (except for periods excluded under 35 $U.S.C.\ 154(b)(1)(B)(i)-(iii))$, and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 $U.S.C.\ 154(b)(1)(B)$ in determining whether periods of delay "overlap" under 35 $U.S.C.\ 154(b)(2)(A)$.

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding 37 CFR 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office, May 26, 2005 to June 2, 2009 (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR $1.702(a)(1)^3$, 326 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the issuance of the Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR $1.702(b)^4$, 372 days of patent term adjustment accrued for Office issuance of the patent more than three years after the date the national stage commenced under 35 U.S.C. 371(b).

The 372 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 326 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 372 days and the 326 days is neither permitted nor warranted. 372 days is the actual number of Accordingly, the days issuance of the patent was delayed. additional period of adjustment of 46 days will be entered by the Office for failing to issue the patent within three years.

In view thereof, the patent term adjustment indicated on the patent should be 371 days.

The Office acknowledges the submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by 371 days.

Telephone inquiries regarding this matter should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

Christina Tartera Donnell Senior Petitions Attorney

Christina Pastera Donnell

Office of Petitions

Copy of DRAFT Certificate of Correction Enclosure:

³A restriction requirement was mailed on April 17, 2008, fourteen months and 326 days after the date of completion of all 35 U.S.C. 371 requirements on March 27, 2006.

⁴As of the date the patent issued on June 2, 2009, the application was pending three years and 372 days.

DRAFT COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT

: 7,541,153 B2

DATED

: Jun. 2, 2009

INVENTOR(S): Fukui, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (325) days

Delete the phrase "by 325 days" and insert – by 371 days--